

TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES AND SERVICES

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FORMS

Form NRH-4 Application for Registration of Radiation Generating Equipment
Form NRH-4a (Additional Machines)
Form NRH 9 Application for Registration of Services for Radiation Sources

NOTE: Attachments are currently not available electronically in this file.
If you need a hard copy or have any questions please contact:

Department of Health and Human Services Regulation and Licensure
Public Health Assurance Division
Consumer Health Services
P.O. Box 95007
Lincoln, NE 68509
(402)471-0560
or e-mail radiation.program@hhss.gov.ne

DRAFT
AUGUST 30, 2006

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 2

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CHAPTER 2 REGISTRATION OF RADIATION GENERATION EQUIPMENT FACILITIES AND SERVICES

SCOPE AND AUTHORITY

2-001.01 180 NAC 2 provides for the registration of radiation generating equipment facilities and for the registration of persons providing radiation generating equipment installation, radiation measurements services such as installation, repair, calibration, demonstration, sales, radiation protection, health physics consultations, radiation measurements, survey and facility shielding reviews. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Rev. Stat. section 71-3501 to 71-3520.

2-001.02 In addition to the requirements of 180 NAC 2, all registrants are subject to the applicable provisions of 180 NAC 1, 4, 5, 6, 8, 9, 10, 15, 16, 17, 18, 20 and 21.

2-002 DEFINITIONS: For purposes of 180 NAC 2:

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of a x-ray system or his/her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Consultation means the act of providing professional or expert advice on radiological matters.

Facility means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

Installation or Install means the assembly, placement, or other actions including but not limited to, initial calibration or operability checks that allow a radiation machine to be used in a new location or after being moved from one location to another.

Radiation Safety Officer (RSO) means an individual who has the knowledge of and the authority and responsibility to apply appropriate radiation protection regulations, and practices, who is specifically named on a certificate of registration, and who is the primary contact with the AgencyDepartment.

Service means the repair, calibration, routine maintenance or other checks or examinations performed on a radiation machine, other than those actions taken during the installation of a radiation machine.

X-ray system means an assemblage of components for the controlled production of x-rays, including but not limited to, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

2-003 EXEMPTIONS

2-003.01 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 180 NAC 2, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (5 μ Sv) per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment will not be exempt.

2-003.02 Radiation generating equipment while in transit or storage incident thereto are exempt from the requirements of 180 NAC 2.

2-003.03 Inoperable x-ray radiation generating equipment is exempt from the requirements of 180 NAC 2. For the purpose of 180 NAC 2, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

2-003.04 Domestic television receivers are exempt from the requirements of 180 NAC 2.

2-004 APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES:

2-004.01 Each person having a radiation generating equipment facility must:

1. Apply for registration of such facility with the AgencyDepartment within thirty (30) days following the commencement of the operation of a radiation generating equipment facility. Application for registration must be completed on form NRH-4 furnished by the AgencyDepartment and contain all the information required by the form NRH-4 and accompanying instructions.
2. A radiation safety officer will be designated on the application form. The radiation safety officer will carry out the following responsibilities:
 - a. Preparing operating and safety procedures and keeping them updated;
 - b. Informing this AgencyDepartment of lost or stolen radiation generating equipment or overexposures;
 - c. Knowing policies and procedures;
 - d. Stopping unsafe practices;
 - e. Keeping records;
 - f. Training employees; and
 - g. Insuring that 180 NAC is followed.
3. Each registrant must prohibit any person from furnishing radiation generating equipment servicing or services as described in 180 NAC 2-005.04 to his/her radiation generating equipment facility until such person provides evidence that (s)he has been registered with the AgencyDepartment as a provider of services in accordance with 180 NAC 2-005. A list of these registrants will be available for distribution by the AgencyDepartment.

4. The AgencyDepartment at any time after the filing of the original application may require further statements in order to enable the AgencyDepartment to determine whether the certification or registration should be issued or denied.
5. Each application for a certificate of registration must be accompanied by the fee prescribed in 180 NAC 18.
6. The applicant's proposed radiation generating equipment, facilities, and operating and safety procedures must be adequate to minimize danger to occupational and public health and safety.
7. To register or reregister sources of radiation, in accordance with rules and regulations adopted and promulgated by the AgencyDepartment, will be subject to a fine.
8. An application for use of a radiation generating equipment must be signed by the applicant and the radiation safety officer if the radiation safety officer is someone other than the applicant.

2-005 APPLICATION FOR REGISTRATION OF SERVICING AND SERVICES

2-005.01 Each person who is engaged in the business of installing radiation generating equipment or is engaged in the business of furnishing radiation generating equipment servicing, radiation measurements, and/or other services must apply for registration of such services with the AgencyDepartment at least 30 days prior to furnishing any such services.

2-005.02 The application for registration must be completed on form NRH-9 furnished by the AgencyDepartment. It must contain all the information required by the form NRH-9 and be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf.

1. The AgencyDepartment at any time after the filing of the original application may require further statements in order to enable the AgencyDepartment to determine whether the certification or registration should be issued or denied.
2. Each application for a certificate of registration must be accompanied by the fee prescribed in 180 NAC 18.

2-005.03 Each person applying for registration under 180 NAC 2 must specify:

1. That (s)he has read and understands the requirements of 180 NAC 2; and
2. The services for which (s)he is applying for registration; and
3. The training and experience that qualify him/her to discharge the services for which (s)he is applying for registration. The applicant must submit to the AgencyDepartment written documentation of the specific training and experience that qualifies each individual to provide the service. (See 180 NAC 15-013 and 15-033).

2-005.04 For the purpose of 180 NAC 2-005, services may include but are not limited to:

1. Installation/Service: This includes installation/assembly (including initial electronic calibration) and the service/repair of radiation generating equipment and associated radiation generating equipment components. It also includes the measurement of radiation output. (See 180 NAC 15-033 for training requirements);
2. Calibration: This includes the calibration of diagnostic radiation generating equipment other than Computed Tomography (CT) facilities (See 180 NAC 15-033 for training requirements), CT (See 180 NAC 15-013.01 and 15-013.02 for training requirements) and therapeutic radiation generating equipment (See 180 NAC 15-013.01 for training requirements);
3. Consultations: This includes health physics consultation for diagnostic radiation generating facilities other than CT facilities (See 180 NAC 15-013.01, 15-013.02 or 15-013.03 for training requirements), CT facilities (See 180 NAC 15-013.01 or 15-013.02 for training requirements), and therapeutic (See 180 NAC 15-013.01 for training requirements);
4. Reviews: This includes area surveys and shielding reviews of diagnostic radiation generating facilities other than CT and therapeutic facilities (See 180 NAC 15-013.01, 15-013.02 or 15-013.03 for training requirements), area surveys and shielding reviews of CT facilities (See 180 NAC 15-013.01, 15-013.02 for training requirements), and area surveys and shielding reviews of therapeutic facilities (See 180 NAC 15-013.01 for training requirements);
5. Demonstration: Demonstration which includes energizing the radiation generating equipment (See 180 NAC 15-013.033); and
6. Sales: This includes the sales of radiation generating equipment. (No training is required.)

2-005.05 No individual may perform services which are not specifically stated for that individual on the certificate of registration issued by the AgencyDepartment.

2-005.06 In addition to the requirements of 180 NAC 2-005.01 through 2-005.05

1. Assemblers, services and servicing personnel must provide the registrant with instruction manuals, manufacturer specifications and other information, as required by the Federal Performance Standard, and these Regulations, which are applicable to the newly installed x-ray systems or components.
2. Applicant's for x-ray facility shielding review must submit procedures.

2-006 ISSUANCE OF CERTIFICATE OF REGISTRATION (NRH-4 AND/OR NRH-9)

2-006.01 Upon a determination that an applicant meets the requirements of the regulations, the AgencyDepartment will issue a Certificate of Registration.

2-006.02 The AgencyDepartment may incorporate in the Certificate of Registration at the time of registration or thereafter by rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation generating equipment, radiation source servicing, radiation measurements and/or services it deems appropriate or necessary in order to:

1. Minimize danger to occupational and public health and safety;
2. Require additional records and keeping of additional records as maybe appropriate or necessary; and
3. Prevent loss or theft of radiation generating equipment subject to Title 180.

2-007 SPECIFIC TERMS AND CONDITIONS OF CERTIFICATES OF REGISTRATION:

2-007.01 Each certificate of registration issued in accordance to 180 NAC 2 will be subject to the applicable provisions of the Nebraska Radiation Control Act, Neb.Rev.Stat. §§ 71-3501 to 17-3520 now or hereafter in effect, and to the applicable rules and order of the Department.

2-007.02 A certificate of registration issued or granted under 180 NAC 2 can not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the AgencyDepartment authorizes the transfer in writing.

2-007.03 Each person registered by the AgencyDepartment for radiation generating equipment use in accordance with 180 NAC 2 will confine use and possession of the radiation generating equipment registered to the locations and purposes authorized in the certificate of registration.

2-007.04 The registrant is responsible for complying with 180 NAC and any conditions of the certificate of registration.

2-008 RESPONSIBILITES OF THE REGISTRANT:

2-008.01 The registrant will notify the AgencyDepartment in writing within thirty (30) days of any change which would render the information contained in the application for registration no longer accurate.

2-008.02 The following criteria applies to temporary replacement radiation generating equipment and radiation generating equipment used for clinical trial evaluations. Radiation generating equipment used for clinical trial evaluations, temporary replacement, or demonstration may be used for up to 60 days without adding the radiation generating equipment to an existing certificate of registration. If the use period will exceed 60 days, the facility will be required to add the radiation generating equipment to their certificate of registration and a fee will be assessed. Radiation generating equipment must be registered in accordance with 180 NAC 2.

No fees will be assessed for the operation of radiation generating equipment for clinical trial evaluations or loaner or demonstration radiation generating equipment used for a period of 60 days or less at a facility with a current certificate of registration.

2-008.03 The following applies to voluntary or involuntary petitions for bankruptcy.

1. Each registrant will notify the AgencyDepartment, in writing, immediately following the filing of voluntary or involuntary petition for bankruptcy.
2. The notification will include the bankruptcy court in which the petition for bankruptcy was filed; and the date of the filing of the petition.
3. A copy of the "petition for bankruptcy" must be submitted to the AgencyDepartment along with the written notification.

2-008.04 Receipt, transfer, and disposal of radiation generating equipment. The registrant will ensure that records of receipt, transfer, and disposal of radiation generating equipment are made and/or maintained for each unit of radiation generating equipment. Records of receipt, transfer, and disposal of radiation generating equipment will include the following:

1. Manufacturer's name and model and serial number from the control panel; and
2. Date of the receipt, transfer, and disposal.

2-008.05 Approval not implied: No person, in any advertisement, will refer to the fact that s/he or his/her facility is registered with the AgencyDepartment pursuant to the provision of 180 NAC 2-004, and no person will state or imply that any activity under such registration has been approved by the AgencyDepartment.

2-008.06 Inventory:

1. Each registrant will annually inventory all radiation generating equipment possessed. The inventory will include the manufacturer's name, model, and serial number of the control panel and will be made and maintained for inspection by the Department in accordance with 180 NAC 4-046.
2. Notification is required within 30 days of any change of radiation generating equipment inventory. This includes installation or removal and the disposition of any equipment disposed of or transferred. The assembler's notification of installation may be accepted in lieu of notification by the registrant. This does not relieve the registrant of the responsibility to assure that proper notification had been made.

2-009 EXPIRATION/TERMINATION OF CERTIFICATE OF REGISTRATION:

2-009.01 Expiration of Certificate:

1. Except as provided by 180 NAC 2-010.02, each certificate of registration will expire annually on the anniversary of the date issued. Expiration does not relieve the registrant of the requirements of 180 NAC 2.
2. If a registrant does not renew the certificate of registration per 180 NAC 2, the registrant will on or before the expiration date on the certificate of registration:

- a. Terminate use of all dental radiation generating equipment;
- b. Submit a record of disposition of the dental radiation generating equipment; and
- c. Pay any outstanding fees per 180 NAC 18-008.

2-009.02 Termination of Registration: If a registrant does not renew the certificate of registration in accordance with 180 NAC 2-009.01, the registrant must on or before the expiration date on the certificate of registration:

1. Terminate use of all radiation generating equipment;
2. Submit a record of disposition of the radiation generating equipment and
3. Pay any outstanding fees per 180 NAC 18.

2-010 RENEWAL OF CERTIFICATE OF REGISTRATION

2-010.01 Application for renewal of Registration must be filed in accordance with 180 NAC 2-004 or 180 NAC 2-005.

2-010.02 In any case in which a registrant has filed an application in proper form for renewal, such existing certificate of registration will not expire until the application status has been finally determined by the AgencyDepartment.

2-011 ASSEMBLER AND/OR TRANSFER OBLIGATION¹

2-011.01 Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation generating equipment or components which affect radiation output in this State must notify the AgencyDepartment within 15 days of:

1. The full name and address of persons who have received this equipment;
2. The manufacturer, model, and serial number of each radiation generating equipment transferred; and
3. The date of transfer of each radiation generating equipment.

2-011.02 No person may make, sell, lease, transfer, lend, assemble, or install radiation generating equipment or the components used in connection with such equipment unless such components and equipment, when properly placed in operation and used, meet the requirements of 180 NAC.

2-012 OUT-OF-STATE RADIATION GENERATING EQUIPMENT

¹In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with requirements of 21 CFR Chapter 1, Section 1020.30(d) attached hereto as pages 611-612, except the stricken text of Attachment Number 2-1 and incorporated herein by this reference, shall suffice in lieu of any other report by the assembler.

DRAFT

NEBRASKA HEALTH AND HUMAN SERVICES

AUGUST 30, 2006

REGULATION AND LICENSURE

180 NAC 2

2-012.01 Except, as provided by 180 NAC 2-008.02, whenever any radiation generating equipment which is registered in another state or by the federal government is to be brought into the State, for any temporary use, the person proposing to bring such equipment into the State shall give written notice to the AgencyDepartment (at least 2 working days) before such equipment is to be used in the State. The notice shall include:

1. The type of radiation generating equipment;
2. The nature, duration, and scope of use; and
3. The exact location(s) where the radiation generating equipment is to be used; and
4. States in which this equipment is registered.

2-012.02 If, for a specific case, the (two working-day) period would impose an undue hardship on the person, upon application to the AgencyDepartment, permission to proceed sooner may be granted.

2-012.03 The person referred to in 180 NAC 2-012 .01 shall:

1. Comply with all applicable regulations of the AgencyDepartment;
2. Supply the AgencyDepartment with such other information as the AgencyDepartment may reasonably request; and
3. Not operate within the State on a temporary basis in excess of 180 calendar days per year.
4. Submit the appropriate fee as specified in 180 NAC 18.

DRAFT
AUGUST 30, 2006

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 2

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NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM
DEPARTMENT OF REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
X-RAY PROGRAM

For ~~Agency~~Department Use Only
Regist. No. _____
State _____ Co. _____
Priority _____ Fee Det. No. _____
Region _____

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Instructions: Type or Print except where indicated. Retain one copy for your files and submit original application to: Nebraska Dept. of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P O Box 95007, Lincoln, NE 68509-5007.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____
Address: _____

City, State Zip: _____
Telephone #: _____
FAX #: _____
eMail Address: _____

1.b Street address(es) at which Radiation Generating Equipment will be used. (If different than 1.a)

(1) Permanent Address: _____

City, State Zip: _____
(2) Temporary Job Sites Throughout Nebraska? ☐ Yes ☐ No

2. Billing Information

Address(if different than 1.a):

Person to Contact: _____
Telephone #: _____

3. Radiation Safety Officer (RSO) (See 180 NAC 2-004.01, item 2)

Title: _____
Telephone #: _____

4. Type of Practice (see Instruction Sheet) _____

5. RADIATION GENERATING EQUIPMENT (USE ADDITIONAL SHEETS IF NECESSARY)

List each machine on a separate line.

[illegible]

6. I do hereby accept the responsibility of radiation safety officer.

Type or Print Name of Radiation Safety Officer from item

Signature of Radiation Safety Officer

Date _____

3.

7. CERTIFICATION

(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge.

Applicant Name from Item 1.a.

By: _____
Signature of certifying official authorized to act on
behalf
of applicant

Date: _____

Print Name and Title of certifying official

Effective Date

Registration No. _____

5a. LIST ADDITIONAL MACHINES ON THIS SHEET

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Model No.	Serial No.	Date Installed	Date Manufactured	Control Room #
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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIATION CONTROL PROGRAM

APPLICATION FOR REGISTRATION OF SERVICES FOR RADIATION GENERATING EQUIPMENT

INSTRUCTIONS: (Use additional sheets where necessary.)

■ **Type or print except where indicated.**

■ **Retain one copy for your files**

■ **Submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.**

■ **Submit annual fee per 180 NAC 18-008.**

■ **Upon approval of the application a "Certificate of Registration for Radiation Generating Equipment." will be issued.**

1. Name and Street Address of Applicant's Business (Individual or Company)

Applicant Name:

Address:

City, State Zip+4

Telephone #:

FAX#

E-mail Address:

2. Name of Person Responsible to Contact Regarding this Application

Name

Telephone #

3. Types of Services to be performed (Please check all appropriate boxes.)

Training Requirements References:

- | | |
|---|--|
| <input type="checkbox"/> A. Installation/Service (If "A" is checked, please check at least one of the 3 items below.) | |
| <input type="checkbox"/> A1. Installation/Assembly (including initial Electronic Calibration) of Radiation Generating Equipment | <u>180 NAC 15-033</u> |
| <input type="checkbox"/> A2. Service/repair of Radiation Generating Equipment | <u>180 NAC 15-033</u> |
| <input type="checkbox"/> A3. Measurement of Radiation output | <u>180 NAC 15-033</u> |
| <input type="checkbox"/> B. Calibration (If "B" is checked, please check at least one the 3 items below) | |
| <input type="checkbox"/> B1. Calibration of Diagnostic Radiation Generating Equipment | <u>180 NAC 15-033</u> |
| <input type="checkbox"/> B2. Calibration of CTs | <u>180 NAC 15-013.01 or 15-013.02</u> |
| <input type="checkbox"/> B3. Calibration of Therapeutic Radiation Generating Equipment | <u>180 NAC 15-013.01</u> |
| <input type="checkbox"/> C. Consultations (If "C" is checked, please check at least one the 3 items below) | |
| <input type="checkbox"/> C1. Health Physics Consultations of Diagnostic Radiation Generating Facilities | <u>180 NAC 15-013.01 or 15-013.02 or 15-013.03</u> |
| <input type="checkbox"/> C2. Health Physics Consultations for CT facilities | <u>180 NAC 15-013.01 or 15-013.02</u> |
| <input type="checkbox"/> C3. Health Physics Consultations for Therapeutic | <u>180 NAC 15-013.01</u> |
| <input type="checkbox"/> D. Reviews (If "D" is checked, please check at least one of the 3 items below.) | |
| <input type="checkbox"/> D1. Area Surveys and shielding reviews of Diagnostic Radiation Generating Facilities | <u>180 NAC 15-013.01 or 15-013.02 or 15-013.03</u> |
| <input type="checkbox"/> D2. CT Shielding Reviews | <u>180 NAC 15-013.01 or 15-013.02</u> |
| <input type="checkbox"/> D3. Therapeutic Reviews | <u>180 NAC 15-013.01</u> |
| <input type="checkbox"/> E. Demonstration which includes energizing the radiation generating equipment | <u>180 NAC 15-033</u> |
| <input type="checkbox"/> F. Sales | <u>No training is required</u> |
| <input type="checkbox"/> G. Other | <u>Dependent on service requested.</u> |

4. Training: (At least one individual must be qualified for each of the requested service(s) listed in 3.A through E and G)

4.A. Submit name of individual qualified and which service the individual is to provide.

4.B. Attach training requirements for each individual. (See item 3. On Page 1 of this form for training requirements references.)

4.C. Each individual applying for registration must read and understand the requirements of 180 NAC 2.

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

**Name of
Individual**

Circle Service(s) Individual is Providing

Al, A2, A3, B1, B2, B3, C1, C2, C3, D1, D2, D3, E, G.

☐ Training Documentation for individual is attached.

☐ This individual has read and understands the requirements of
180 NAC 2

Use additional sheet(s) for additional names and information

IF APPLICABLE

5. Attach procedures for x-ray facility shielding reviews. (See 180 NAC 2-006.04, item 3)

6. CERTIFICATION
(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.. certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____

Signature

Date: _____

Print Name and Title of certifying official authorized to act on behalf of the applicant

Registration Does Not Imply Approval or Disapproval of Service

**NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM**

APPLICATION FOR REGISTRATION OF SERVICES FOR RADIATION SOURCES

INSTRUCTIONS—(Use additional sheets where necessary.)

Type or Print except where indicated.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1. Name and Street Address of Applicant (Individual or Company)

Applicant Name: _____

Address: _____

City, State Zip+4 _____

Telephone #: _____

FAX#: _____

E-mail Address: _____

2. Person to Contact Regarding this Application

Telephone # _____

3. Individual User(s)

Submit in duplicate on a separate sheet(s) the Name and Title of individual(s) qualified to perform each service listed below. Document training and experience in accordance with 180 NAC 15.

4. Services Provided (check as appropriate)

Radioactive Material Services Requiring Registration and an Agency, NRC or Agreement State Specific License:

- ☐ —Analysis of Samples for Radioactivity
- ☐ —Bioassay
- ☐ —Calibration of Radiation monitoring Instruments
- ☐ —Decommissioning of Facilities
- ☐ —Decontamination of Facilities
- ☐ —Facility/Packaging Shielding Determination (Use of Radioactive Material)
- ☐ —Leak Test Service
- ☐ —Waste Disposal Services (Receipt of Waste)

(continued)

~~4. Services Provided (check as appropriate) (Continued)~~

~~Radioactive Material Services Requiring Registration:~~

~~☐ Waste Disposal Consultation Services (No Receipt of Waste)~~

~~Radiation Generating Equipment Services Requiring Registration:~~

~~☐ Device Sales~~

~~☐ Device Services (Demonstration, Installation, Electronic Calibration, Repair, Survey)~~

~~General Radiation Services Requiring Registration:~~

~~☐ Facility/Packaging Shielding Review (Calculation Only) Submit Procedures~~

~~☐ Radiation Protection or Health Physics Consultation~~

~~☐ Radiation Survey Submit Instrumentation and Procedures~~

~~☐ Personnel Monitoring Submit NVLAP Certification~~

~~☐ Other~~

5. CERTIFICATION

(This Item must be completed by applicant.)

~~The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any Supplements attached hereto, is true and correct to the best of our knowledge and belief.~~

Applicant Name From Item 1.

By: _____ Date: _____
Signature

Print Name and Title of certifying official authorized to act on behalf of the applicant

Registration Does Not Imply Approval or Disapproval of Service

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DRAFT
AUGUST 30, 2006

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 2

ATTACHMENT 2-1

21 CFR 1020.30(d)

DRAFT
AUGUST 30, 2006

NEBRASKA HEALTH AND HUMAN SERVICES
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Food and Drug Administration, HHS

§ 1020.30

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Compliance and Surveillance of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

(d) *Assemblers' responsibility.* An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by §§ 1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements.* Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to the Center for Devices and Radiological Health in the report required under § 1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.

Signature

Company Name

Street Address, P.O. Box

City, State, Zip Code

Date of Installation

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The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in §1010.3 of this chapter, manufacturers of components subject to this section and §§1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized pursuant to paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified pursuant to paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels, that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement

tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, he shall provide necessary information to allow the assembler to determine the